PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 14187/PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB 03/00074	International filing date *(day/month/year)* 09.01.2003	Priority date *(day/month/year)* 07.02.2002
International Patent Classification (IPC) or both national classification and IPC C08B37/08		
Applicant ABBOTT LABORATORIES DE COSTA RICA LTD et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28.07.2003	29.04.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Contet, F Telephone No. +49 89 2399-8671

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/00074

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-7 as originally filed

Claims, Numbers

1-7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-7
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-7
Industrial applicability (IA)	Yes:	Claims	1-7
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: PATENT ABSTRACTS OF JAPAN vol. 012, no. 223 (C-507), 24 June 1988 (1988-06-24) & JP 63 017901 A (HIGETA SHOYU KK), 25 January 1988 (1988-01-25) & DATABASE WPI Section Ch, Week 198809 Derwent Publications Ltd., London, GB; Class D17, AN 1988-061314 & JP 63 017901 A (HIGETA SHOKYU KK), 25 January 1988 (1988-01-25)

D2: WO 91 00298 A (FIREXTRA OY) 10 January 1991 (1991-01-10)

D3: WO 01 87988 A (THE PROCTER / GAMBLE COMPANY) 22 November 2001 (2001-11-22)

D4: PATENT ABSTRACTS OF JAPAN vol. 012, no. 186 (C-500), 31 May 1988 (1988-05-31) & JP 62 292802 A (HIGETA SHOYU KK), 19 December 1987 (1987-12-19) & DATABASE WPI Section Ch, Week 198805 Derwent Publications Ltd., London, GB; Class D17, AN 1988-033032 & JP 62 292802 A (HIGETA SHOKYU KK), 19 December 1987 (1987-12-19)

I- Preliminary remarks:

From the point of view of patent law a chemical production process is clearly defined by a statement of the initial substances, the process parameters and the endproduct and as to how it can be subsequently carried out.
Moreover, when identical process features are applied to the same starting products, then identical endproducts will be obtained.

II- Novelty:

D1 discloses a process wherein the deacetylation product of chitin is adjusted to pH ≥6 to obtain a precipitate. This precipitate is washed, dissolved in an acid (acetic acid, hydrochloric acid, sulfuric acid) and adjusted to pH ≥6 with an alkali to precipitate chitosan. These procedures of washing, dissolution and precipitation are repeated to improve the purity of the end product chitosan.
Keeping in mind the previous point, the subject-matter of claims 1 to 7 is not new

over D1.

D2, the cited passages, disclose a process for the continuous manufacture of microcrystalline chitosan. Thus, an acidic solution of chitosan is treated with an aqueous sodium hydroxide. After a passage in a compensation tank, the chitosan dispersion is delivered into a purification installation. the subject-matter of claims 1-4,6 and 7 is not new over D2.

The process features disclosed in D3, the cited passages, do not differ from the process features according to the present claims. The subject-matter of claims 1 to 7 is not new over D3.

D4 discloses the isolation of chitosan from a deacetylation liquor of chitin. Thus, in a first step, the pH is adjusted to 7-9 by adding a salt and optionally sodium hydroxide. The deposit of chitosan is separated by means of centrifugation and filtration, and redissolved in an acid (acetic or chlorhydric acid). Again the pH is adjusted to 7-9 to allow chitosan to deposit. These steps of washing, dissolving and forming deposit of chitosan can be repeated to perform purification.
These steps are identical to the process claimed and the subject-matter of claims 1-4, 6 and 7 is not new over D4.

III- Inventive step:

Novelty cannot be acknowledged and examination of an inventive step is rendered superfluous. However, attention should be paid to the examples which are not carried out according to the description and the claims (see the reasons given in point IV).

IV-Article 6 PCT:

Claim 1 is not supported by the description as required by Article 6 PCT for the following reason. According to claim 1, step 1, a chitosan having a protein content ≥ 0.001% is purified. This definition is inconsistent with the disclosure on p.2, l.15 o to 16 of the description, wherein the polymer concentration is ≥ 0.001%. In this case, the term polymer can refer to both the chitosan and/or the protein.

According to the description on page 2 l.13-24, the chitosan, dissolved in an acidic solution, is agglomerated with an aqueous solution of an alkali. Then the

precipitated product is subjected to a basic solution (conc. ≥ 0.1wt%, preferably 1-10wt%). The protein solution is separated from the precipitated chitosan, which is washed and dried. Thus, the fact to carry out the reacting step in two steps seems an essential feature of the invention.
Since independent claim 1 does not contain this feature it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

Furthermore, claim 4 is not consistent with the description since only the first step of the reacting step is carried out at pH 6-6.5 (PCT Guidelines C III 4.3 and 4.4). But example 1 is not carried out accordingly since the first agglomeration step is carried out at pH 8.2 and the concentration ratio of alkali according to claim 5 is not fulfilled (0.75/5). Furthermore, the method of detection of the protein and especially the detection limit have not been indicated.